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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/650,337	08/28/2000	William J. Dower	16528A-000461US	8260
35938 7	2590 06/24/2005		EXAMINER	
BIOTECHNOLOGY LAW GROUP			WANG, LOUISE Z	
C/O PORTFO			ARTIBUT	DADED MIRADED
P.O. BOX 52050		ART UNIT	PAPER NUMBER	
MINNEAPOLIS, MN 55402			1648	

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/650,337	DOWER ET AL.				
Office Action Summary	Examiner	Art Unit				
	Louise Wang	1648				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 28 Au	1)⊠ Responsive to communication(s) filed on 28 August 2000.					
2a) ☐ This action is FINAL . 2b) ☑ This	☐ This action is FINAL . 2b) ☑ This action is non-final.					
3) Since this application is in condition for allowar	nce except for formal matters, pro	secution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>33-73</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8)⊠ Claim(s) <u>33-73</u> are subject to restriction and/or election requirement.						
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail Da					
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DETAILED ACTION

Applicant's Preliminary Amendment, filed August 28, 2000, is acknowledged.

Claims 1-32 have been canceled.

Claims 33-73 have been added.

Claims 33-73 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 33, 37, 44-46, 57, 58, 61, 62, 64, and 65, drawn to a method of identifying peptides with binding properties, classified in class 435, subclass 7.1.
- II. Claims 34, 40, and 43, drawn to peptides, classified in class 530, subclass 300.
- III. Claims 35, 38, 45-47, 50-55, and 63, drawn to a method of isolating DNA, classified in class 435, subclass 6.
- IV. Claims 36, 41, and 56 drawn to polynucleotides, classified in class 536, subclass23.1.
- V. Claims 39, 42, 49, 69, and 70, drawn to vectors comprising polynucleotide sequences encoding diverse peptides, classified in class 435, subclass 320.1.
- VI. Claims 35, 38, 45-48, 50-55, and 63, drawn to a method of isolating RNA, classified in class 435, subclass 6.
- VII. Claims 59 and 60, drawn to a method of detection or titration of a ligand using a peptide, classified in class 435, subclass 7.1.

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VIII. Claims 66-68, and 71-73, drawn to a process for the production of expression vectors, classified in class 435, subclass 320.1.

The inventions are distinct, each from the other because:

Inventions (I, III, VI, VIII) and (II, IV, V) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the polynucleotides of Group IV, the polypeptides of Group II, and the vectors of Group V can be isolated by methods other than recited in Groups I, III, VI, and VIII, for instance, by purification from natural resources and chemical synthesis.

Group II is distinct from Groups (IV and V) as different chemical entities. Group II is a peptide composed of amino acids and Groups (IV and V) are genes or expression vectors directed to nucleic acids. Each has a different chemical composition, structure, function, and physiological activity.

Groups II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptide as claimed in Group II can be used in a different method such as the development of an antibody, whereas the method as claimed in Invention VII can use a different receptor.

Groups I, III, and VI-VIII are different methods with respect to ingredients, protocol procedures, and end products; therefore, each method is patentably distinct.

Inventions IV and V are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product, an oligonucleotide, is deemed to be useful as a probe in hybridization and as an aptamer, interference RNA or anti-sense oligonucleotide for target sequence binding and inhibition. The inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Furthermore, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Louise Wang Patent Examiner June 17, 2005

> JEFFREY STUCKER PRIMARY EXAMINER